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**DEC 15 2008**

**OFFICE OF PETITIONS**

In re Application of  
Roninson, et al.  
Application No.: 10/520,142  
Filing Date: 18 August, 2005  
Attorney Docket No. 99,216-KK6

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: DECISION  
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This is a decision on the petition filed on 22 September, 2008, and properly considered as a petition requesting withdrawal of the holding of abandonment under 37 C.F.R. §1.181.

The petition to withdraw the holding of abandonment under 37 C.F.R. §1.181 is **GRANTED**.

As to the Request to Withdraw  
the Holding of Abandonment

Petitioners always are directed to the Commentary at MPEP §711.03(c)(I) for guidance as to the proper showing and timeliness requirements for relief under 37 C.F.R. §1.181.

BACKGROUND

The record reflects that:

Petitioner failed to reply timely and properly to the Requirement for Restriction mailed on 10 January, 2008, with reply due absent extension of time on or before 10 February, 2008.

The application went abandoned after midnight 10 February, 2008.

The Office mailed a Notice of Abandonment on 5 September, 2008.

On 22 September, 2008, Petitioner filed a petition seeking withdrawal of the holding of abandonment under the provisions of 37 C.F.R. §1.181, and averred, *inter alia*, non-receipt due to the Office error of mailing the Office action to an incorrect address—that of former Counsel rather than to present Counsel/Petitioner, the latter of whom filed a Revocation/Power of Attorne with a certificate pursuant to 37 C.F.R. §3.73(b) on 25 September, 2006, which was

acknowledged as accepted by the Office on 25 October, 2006, but apparently not entered. While Petitioner acknowledged having received the Notice of Abandonment from prior Counsel, Petitioner was silent as to receipt/nonreceipt of the Office action/Restriction (a copy of which is enclosed herewith) from prior Counsel, and did not submit a reply thereto.

Thus, Petitioner appears to have satisfied the showing requirements under the rule as set forth at MPEP §711.03(c)(I).

The availability of applications and application papers online to applicants/practitioners who diligently associate their Customer Number with the respective application(s) now provides an applicant/practitioner on-demand information as to events/transactions in an application. Thus, now if one wishes to know the progress in and/or status of an application or the accuracy of the data therein, one need only look at the file online.

Out of an abundance of caution, Petitioners always are reminded that those registered to practice *and* all others who make representations before the Office must inquire into the underlying facts of representations made to the Office and support averments with the appropriate documentation—since all owe to the Office the continuing duty to disclose.<sup>1</sup>

### STATUTES, REGULATIONS

Congress has authorized the Commissioner to "revive an application if the delay is shown to the satisfaction of the Commissioner to have been "unavoidable." 35 U.S.C. §133 (1994). And the regulations at 37 C.F.R. §1.137(a) and (b) set forth the requirements for a Petitioner to revive a previously unavoidably or unintentionally, respectively, abandoned application.<sup>2,3</sup>

Moreover, the Office has set forth in the Commentary at MPEP §711.03(c)(I) the showing and timeliness requirements for a proper showing for relief under 37 C.F.R. §1.181 in these matters.

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<sup>1</sup> See supplement of 17 June, 1999. The Patent and Trademark Office is relying on petitioner's duty of candor and good faith and accepting a statement made by Petitioner. See Changes to Patent Practice and Procedure, 62 Fed. Reg. at 53160 and 53178, 1203 Off. Gaz. Pat. Office at 88 and 103 (responses to comments 64 and 109)(applicant obligated under 37 C.F.R. §10.18 to inquire into the underlying facts and circumstances when providing statements to the Patent and Trademark Office). See specifically, the regulations at 37 C.F.R. §10.18.

<sup>2</sup> See: Changes to Patent Practice and Procedure; Final Rule Notice, 62 Fed. Reg. at 53158-59 (October 10, 1997), 1203 Off. Gaz. Pat. Office at 86-87 (October 21, 1997).

<sup>3</sup> The language of 35 U.S.C. §133 and 37 C.F.R. §1.137(a) is clear, unambiguous, and without qualification: the delay in tendering the reply to the outstanding Office action, as well as filing the first petition seeking revival, must have been unavoidable for the reply now to be accepted on petition. (Therefore, by example, an unavoidable delay in the payment of the Filing Fee might occur if a reply is shipped by the US Postal Service, but due to catastrophic accident, the delivery is not made.) Delays in responding properly raise the question whether delays are unavoidable. Where there is a question whether the delay was unavoidable, Petitioners must meet the burden of establishing that the delay was unavoidable within the meaning of 35 U.S.C. §133 and 37 C.F.R. §1.137(a). And the Petitioner must be diligent in attending to the matter. Failure to do so does not constitute the care required under Pratt, and so cannot satisfy the test for diligence and due care. (By contrast, unintentional delays are those that do not satisfy the very strict statutory and regulatory requirements of unavoidable delay, and also, by definition, are not intentional.))

Allegations as to the Request to  
Withdraw the Holding of Abandonment

The record evidences a satisfactory presentation of the showing requirements under the Rule.

CONCLUSION

The petition as considered under 37 C.F.R. §1.181 is **granted**, and the 5 September, 2008, Notice of Abandonment is **vacated**.

The instant application is released to Technology Center/AU (TC/AU) 1642 for further processing in due course—including the remailing of the 10 January, 2008, Office action.

Petitioner may find it beneficial to view Private PAIR within a fortnight of the instant decision to ensure that the revival has been acknowledged by the TC/AU in response to this decision. It is noted that all inquiries with regard to that change in status need be directed to the TC/AU where that change of status must be effected—that does not occur in the Office of Petitions.

Telephone inquiries regarding this decision may be directed to the undersigned at (571) 272-3214—it is noted, however, that all practice before the Office is in writing (see: 37 C.F.R. §1.2<sup>4</sup>) and the proper authority for action on any matter in this regard are the statutes (35 U.S.C.), regulations (37 C.F.R.) and the commentary on policy (MPEP). Therefore, no telephone discussion may be controlling or considered authority for Petitioner's action(s).



/John J. Gillon, Jr./  
John J. Gillon, Jr.  
Senior Attorney  
Office of Petitions

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<sup>4</sup> The regulations at 37 C.F.R. §1.2 provide:

**§1.2 Business to be transacted in writing.**

All business with the Patent and Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.



# UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/520,142

08/18/2005

Igor B. Roninson

99,216-KK6

5577

20306 7590 01/10/2008  
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EXAMINER

GODDARD, LAURA B

ART UNIT

PAPER NUMBER

1642

MAIL DATE

DELIVERY MODE

01/10/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/520,142	<b>Applicant(s)</b> RONINSON ET AL.	
	<b>Examiner</b> Laura B. Goddard, Ph.D.	<b>Art Unit</b> 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 January 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1,2,4,7-10,13,14,16,19-23,26,27,29-31,34,35,37-39,42,43,45,48,49,51,52,55,56,58,61-65,68,69,71-73,76,77,79-81,86-92,97-99,102,104 and 108-111 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**Continuation of Disposition of Claims: Claims pending in the application are 1,2,4,7-10,13,14,16,19-23,26,27,29-31,34,35,37-39,42,43,45,48,49,51,52,55,56,58,61-65,68,69,71-73,76,77,79-81,86-92,97-99,102,104 and 108-111.**

***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

**NOTE: Claim 50 is withdrawn because it is dependent on a canceled claim.**

Group 1, claim(s) 1, 2, 4, 7, 8, 9, 10, 13, 14, 16, 19, 20-23, 26, 27, 29-31, 34, 35, 37-39, drawn to the special technical feature of a method for identifying a compound that induces senescence in a mammalian cell comprising culturing a mammalian cell, in the presence and absence of the compound; assaying the expression of at least one cellular gene in **Table 2A** in said cell in the presence of the compound with the expression of said gene in the cell in the absence of the compound; and identifying compounds that induce senescence when expression of at least one cellular gene in **Table 2A** is higher in the presence of the compound than in the absence of the compound.

**Additionally, Applicants must elect a single or specific combination of genes from Table 2A.** Each gene is structurally and functionally distinct and lacks the same or corresponding special technical features.

Group 2, claim(s) 42, 43, 45, 48, 49, 51, 52, 55, 56, 58, 61-65, 68, 69, 71-73, 76, 77, 79-81 drawn to the special technical feature of a method for identifying a compound that induces senescence in a mammalian cell comprising culturing a mammalian cell in the presence and absence of the compound; assaying the expression of at least one cellular gene in **Table 1** in said cell in the presence of the compound with the expression of said gene in the cell in the absence of the compound; and identifying compounds that induce senescence when expression of at least one cellular gene in **Table 1** is lower in the presence of the compound than in the absence of the compound.

**Additionally, Applicants must elect a single or specific combination of genes from Table 1.** Each gene is structurally and functionally distinct and lacks the same or corresponding special technical features.

Group 3, claim(s) 86-92, drawn to the special technical feature of a method for assessing the efficacy of a treatment of a disease or condition relating to abnormal cell proliferation or neoplastic cell growth, the method comprising: obtaining a biological sample comprising cells from an animal having a disease or condition relating to abnormal cell proliferation or neoplastic cell growth before treatment and after treatment; comparing expression of at least one gene in **Table 1**, **2A**, or **2B** after treatment with expression of said gene(s) before treatment; and determining that said treatment has efficacy for treating the disease or condition relating to abnormal cell proliferation or neoplastic cell growth if expression of at least one gene in **Table 2A** and



2B is higher after treatment than before treatment or expression of at least one gene in Table 1 is lower after treatment than before treatment.

**Additionally, Applicants must elect a single or specific combination of genes from Table 1, 2A, or 2B. Each gene is structurally and functionally distinct and lacks the same or corresponding special technical features.**

Group 4, claim(s) 97-99, 102, 104, drawn to the special technical feature of a method for identifying a compound that inhibits senescence-associated induction of cellular gene expression comprising: (a) contacting the cell with a cytotoxic agent at a concentration of said agent that inhibits cell growth; (b) assaying the cell in the presence and absence of the compound for changes in expression of cellular genes induced when cells become senescent; (c) and identifying the compound as an inhibitor of senescence-associated induction of cellular gene expression if expression of the cellular genes of (b) is induced in the absence of the compound but is not induced in the presence of the compound.

Group 5, claim(s) 108-111, drawn to the special technical feature of a method for determining treatment efficacy in an animal treated with a compound that induces cellular senescence, comprising: assaying a biological fluid from the animal before and after treatment for a senescence marker; and determining that the treatment is effective

when the amount of the marker detected after treatment is greater than the amount of the marker detected before treatment.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups I-V encompass different special technical features identified in the groupings above. The inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because under unity of invention between different categories of inventions, unity of invention will only be found to exist if specific combinations of inventions are present.

The allowed combinations do not include multiple methods of using products, as claimed in the instant application. The methods do not share the same method steps, objectives, response variables, and/or criteria for success. Since multiple methods with different special technical features are claimed, Groups I-V are not so linked as to form a single general inventive concept and restriction is proper.

## **SPECIES ELECTION**

### **Species Election for Group I**

**A.** This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of mammalian cell are as follows:

**(1) recombinant mammalian cell comprising a reporter gene operably linked to a promoter from a cellular gene in Table 2A) (claims 8, 20, 22, 26, 34, 38 and claims dependent on these); or**

**(2) a non-recombinant mammalian cell.**

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each cell is structurally and functionally distinct requiring different agents, mechanisms of action, method steps, and criteria for success to accomplish the assay.

**B.** This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of mammalian cell are as follows (claims 2, 14, 27, 35):

**(1) p53 deficient cell;**

**(2) tumor cell; or**

**(3) p53 deficient tumor cell.**

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each cell is structurally, physiologically, and functionally distinct.

C. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of expression detection are as follows (claims 4, 10, 16, 23, 31, 39):

- (1) hybridization to a complementary nucleic acid;**
- (2) using an immunological reagent; or**
- (3) assaying for an activity of the cellular gene product.**

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each assay step requires distinct methods steps, reagents, response variables and criteria for success.

D. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of methods are as follows:

- (1) further comprising the step of: assaying expression of one or more genes in Table 2B; and identifying compounds wherein expression of the genes in Table 2B is not greater in the presence of the compound than in the absences of the compound (claim 9 or 30);**

- (2) further comprising assaying the mammalian cell for cell growth and morphological features of senescence; and identifying compounds that induce**

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**If Applicant elects species “(1)” or “(3)” in D above, Applicants must elect a species in E below:**

E. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of cellular gene are as follows:

**Pick one or a specific combination of gene(s) from Table 2B.**

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each gene is structurally and functionally distinct.

#### **Species Election for Group II**

**NOTE: There is no antecedent basis of a “recombinant” mammalian cell as recited in claims 55 and 76.**

F. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of mammalian cell are as follows:

**(1) recombinant mammalian cell comprising a reporter gene operably linked to a promoter from a cellular gene in Table 2A) (claims 49, 55, 62, 63, 62, 68, 72, 76, 80 and claims dependent on these); or**

**(2) a non-recombinant mammalian cell.**

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each cell is structurally and functionally distinct requiring different agents, mechanisms of action, method steps, and criteria for success to accomplish the assay.

**G.** This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of mammalian cell are as follows (claims 43, 56, 69, 77):

- (1) p53 deficient cell;**
- (2) tumor cell; or**
- (3) p53 deficient tumor cell.**

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each cell is structurally, physiologically, and functionally distinct.

**H.** This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of expression detection are as follows (claims 45, 52, 58, 65, 73, 81):

- (1) hybridization to a complementary nucleic acid;**
- (2) using an immunological reagent; or**
- (3) assaying for an activity of the cellular gene product.**

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each assay step requires distinct methods steps, reagents, response variables and criteria for success.

I. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of methods are as follows:

**(1) further comprising the step of: assaying expression of one or more genes in Table 2B; and identifying compounds wherein expression of the genes in Table 2B is not greater in the presence of the compound than in the absences of the compound (claim 51 or 72);**

**(2) further comprising assaying the mammalian cell for cell growth and morphological features of senescence; and identifying compounds that induce senescence when expression of at least one cellular gene in Table 1 is lower in the presence of the compound than in the absence of the compound and the cells**



**are growth-inhibited and express morphological features of senescence in the presence of the compound (claim 55 or 76);**

**(3) further comprising assaying the mammalian cell for cell growth and morphological features of senescence; and identifying compounds that induce senescence when expression of at least one cellular gene in Table 1 is lower in the presence of the compound than in the absence of the compound and the cells are growth-inhibited and express morphological features of senescence in the presence of the compound (claim 55 or 76) and a method of claim 55 or 62 or 76 further comprising the steps of: assaying expression of one or more genes in Table 2B; and identifying compounds wherein expression of the genes in Table 2B is not greater in the presence of the compound than in the absence of the compound (claim 63 or 64 or 80); or**

**(4) not further comprising assaying additional genes in Table 2B or assaying for cell growth and morphological features of senescence.**

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each method is distinct requiring different method steps, objectives, response variables, and/or criteria for success.

**If Applicant elects species “(1)” or “(3)” in I above, Applicants must elect a species in J below:**

J. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of cellular gene are as follows:

**Pick one or a specific combination of gene(s) from Table 2B.**

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each gene is structurally and functionally distinct.

#### **Species Election for Group III**

K. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of expression detection are as follows (claim 92):

**(1) hybridization to a complementary nucleic acid;**

**(2) using an immunological reagent; or**

**(3) assaying for an activity of the cellular gene product.**

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each assay step requires distinct methods steps, reagents, response variables and criteria for success.

**Species Election for Group IV**

**L.** This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of cellular gene are as follows (claim 98 or 104):

**Pick ONE or a specific combination of genes from claim 98 or 104.**

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each gene is structurally and functionally distinct.

**M.** This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of expression detection are as follows (claim 99):

**(1) hybridization to a complementary nucleic acid;**

**(2) using an immunological reagent; or**

**(3) assaying for an activity of the cellular gene product.**

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each assay step requires distinct methods steps, reagents, response variables and criteria for success.

**N.** This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of mammalian cell are as follows (claim 102):

- (1) p53 deficient cell;**
- (2) tumor cell; or**
- (3) p53 deficient tumor cell.**

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each cell is structurally, physiologically, and functionally distinct.

**O.** This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of mammalian cell are as follows:

- (1) recombinant mammalian cell comprising a recombinant expression construct (claim 104); or**
- (2) a non-recombinant mammalian cell.**

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each cell is

structurally and functionally distinct requiring different agents, mechanisms of action, method steps, and criteria for success to accomplish the assay.

### **Species Election for Group V**

**P.** This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of senescence marker are as follows (claim 109):

**Pick ONE marker from claim 109.**

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each marker is structurally and functionally distinct.

**Q.** This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of expression detection are as follows (claim 111):

**(1) hybridization to a complementary nucleic acid;**

**(2) using an immunological reagent; or**

**(3) assaying for an activity of the cellular gene product.**

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each assay step requires distinct methods steps, reagents, response variables and criteria for success.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura B. Goddard, Ph.D. whose telephone number is (571) 272-8788. The examiner can normally be reached on 7:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Laura B Goddard, Ph.D.  
Examiner  
Art Unit 1642